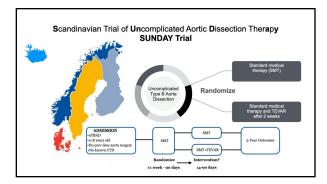


Golden opportunity in Nordic countries

- Similar standards of treatment- equipoise
- State-run health care systems- no financial conflicts of interest
- Centralization of these patients
- Robust registries for data validation





Sample size- "event driven"

- Literature supports 5-year mortality of 20%
 INSTEAD-XL identifies reduction 19.3% to 11.1%
- HR = 0.52
- Two-sided significant level (alpha): 5%
- Power: 80%
- Withdrawal probability: 3%
- Estimated number of event (deaths) = 80
- Estimated sample size: 550 (275 in each arm)



Exclusion

- Life expectency < 2 years
- Known connective tissue disease
- Previous descending aortic surgery
- A co-existing pathology that requires TEVAR
- Pre-existing thoracoabdominal aortic aneurysm
- Sepsis
- Dementia

Follow-up: per protocol

- 3 months, 1 year, 3 years, and 5 years
- Theoretically, all of this can be done over the telephone
- All other visits, readmissions, reinterventions are added





